Nos. 2023-2397, -2398

In the United States Court of Appeals for the Federal Circuit

STRYKER EUROPEAN OPERATIONS HOLDINGS LLC.

Appellant,

v.

OSTEOMED LLC,

Appellee.

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2022-00487 and IPR2022-00488.

REPLY BRIEF OF APPELLANT STRYKER EUROPEAN OPERATIONS HOLDINGS LLC

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TABLE OF ABBREVIATIONS

Abbreviation	Description			
'713 Patent	U.S. Patent No. 9,078,713			
'751 Patent	U.S. Patent No. 10,993,751			
Board	Patent Trial & Appeal Board			
FWD	Final Written Decision			
Holmes	Dr. George Holmes, Stryker's expert			
IPR	Inter Partes Review			
Leinsing	Karl Leinsing, Stryker's expert			
OsteoMed	Petitioner and Appellee, OsteoMed LLC			
POSITA	Person of Ordinary Skill in the Art			
Companion Cases on Appeal	Appeal No. 23-1925(lead) regarding IPR2021-01450, IPR2021-01451, IPR2021-01452, IPR2021-01453, IPR2022-00189, IPR2022-00190, and IPR2022-00191 filed by Stryker against OsteoMed's Patents			
Sherman	Michael Sherman, OsteoMed's expert			
Stryker	Patent Owner and Appellant, Stryker European Holdings LLC			

INTRODUCTION

The Challenged Patents describe an inventive bone plate having a formation that orients a screw at an angle to enhance compression between bones. OsteoMed's Response ignores that the Challenged Patents unambiguously describe *two* separate embodiments: one in which the formation is a deformable angled tab with a hole, and a second embodiment in which the formation itself is an angled hole. While the Challenged Claims are expressly directed to the angled hole embodiment, OsteoMed argues that Stryker's proposed claim constructions improperly exclude the angled tab embodiment, which OsteoMed dubs the sole "preferred embodiment." In this manner, OsteoMed tries to justify the Board's legally erroneous claim constructions.

Additionally, no substantial evidence supports the Board's obviousness findings. OsteoMed chose not to submit a reply declaration after realizing that the conclusory opinions of its expert, Mr. Sherman, regarding an alleged motivation to combine were inconsistent with its positions in the companion cases. This left Stryker's expert opinions unrebutted. With no rebuttal evidence to support a reason to combine Arnould and Zahiri, OsteoMed morphed its Ground 4 obviousness arguments to address Arnould alone. The Board erred by allowing OsteoMed to change its position, by filling in evidentiary gaps for OsteoMed, and by unwittingly incorporating OsteoMed's mistakes into its FWDs. This Court should reverse or vacate and remand to allow the Board to address the Slater grounds.

ARGUMENT

I. THE COURT SHOULD REVERSE OR VACATE THE BOARD'S OBVIOUSNESS FINDING FOR THE '713 PATENT (GROUNDS 4 AND 5)

In IPR2022-00487, OsteoMed's Petition provided five grounds of alleged obviousness:

Petitioner requests the institution of IPR and the cancellation of the Challenged Claims on the following Grounds:					
Ground	Basis	Reference(s)	Claim(s)		
1	§103	WIPO Pat. Pub. No. WO 2007/131287A1 to Slater (Ex. 1004)	32, 33, 36, 37		
2	§103	Slater and U.S. Pat. Pub. No. 2006/0241608 to Myerson et al. ("Myerson") (Ex. 1008)	34, 35, 39		
3	§103	Slater and U.S. Pat. No. 8,187,276 to Zahiri et al. ("Zahiri") (Ex. 1007)	32, 33, 38		
4	§103	E.P. Patent 1897509 to Arnould ("Arnould") (Ex. 1005) and Zahiri	32, 33, 36-39		
5	§103	Arnould, Zahiri, and Myerson	34, 35		

Appx141. Arnould alone was not one of them. Unlike Ground 1, where OsteoMed explicitly presented an obviousness defense based solely on Slater, OsteoMed's Ground 4 (Arnould + Zahiri) arguments were presented in a manner similar to Ground 3 (Slater + Zahiri). Appx146, Appx191-219.

The Board's obviousness finding relating to Challenged Claims 32-39 of the '713 patent should be reversed or vacated and remanded because the Board's

construction of "third hole being angled relative to a longitudinal axis of the plate through a thickness of the plate" ([32f], "the 'angled hole' limitation") was legally erroneous and because its obviousness findings relating to that limitation were unsupported by substantial evidence.

The Board's obviousness finding as to dependent claim 38 should be reversed and remanded for the additional reason that there is no substantial evidence to support a finding that Arnould alone or in view of Zahiri renders obvious the claimed "step of inserting a temporary fixation pin into a hole in the plate to temporarily affix the plate to bone."

A. The Board's Analysis of the "Angled Hole" Limitation was Both Legally Erroneous and Unsupported by Substantial Evidence

Under a proper construction of the "angled hole" limitation, Arnould cannot alone render obvious the Challenged Claims. While Stryker does not dispute that Zahiri discloses an angled hole, the Board's Institution Decision recognized that OsteoMed's reasoning for combining Arnould and Zahiri "lacks detail." Appx327. Since OsteoMed provided *no* additional evidence beyond what was presented with its Petition, the Board's reason for combining Arnould and Zahiri is unsupported by substantial evidence.

1. The Board's Implicit Construction of the Angled Hole Limitation was Legally Erroneous

As a matter of law, a POSITA would understand that the claimed "third hole being angled relative to a longitudinal axis of the plate through a thickness of the plate" requires the third hole itself to be angled, not merely the axis of the third hole as the Board found.

a. Stryker Did Not Forfeit its Claim Construction Argument

OsteoMed contends that Stryker forfeited any right to dispute the Board's construction of the "angled hole" limitations because neither party requested construction below. That is not the law. Where, as here, the Board's obviousness analysis implicitly but erroneously construes a claim term, the erroneous claim construction can and should be reviewed *de novo* on appeal. *Apple Inc. v. MPH Techs. Oy*, No. 2021-1355, 2022 WL 4103286, at *4 (Fed. Cir. Sept. 8, 2022) (finding no forfeiture "where neither party disputed the construction of a term and the Board nevertheless issued a *sua sponte* construction in its final written decision that diverged from the parties' understanding of the claim"); *HTC Corp. v. Cellular Commc'ns Equip., LLC*, 877 F.3d 1361, 1367 (Fed. Cir. 2017); *Carrum Techs., LLC v. Unified Pats., LLC*, No. 2020-2204, 2021 WL 3574209, at *5 (Fed. Cir. Aug. 13, 2021).

OsteoMed certainly cannot claim prejudice or waiver, as Stryker has steadfastly maintained from the outset that the "angled hole" limitations require the third hole itself to be angled. Appx416-417, Appx3442-3443, Appx582-583, Appx3567-3568, *see also Summit 6, LLC v. Samsung Elecs. Co. Ltd.*, 802 F.3d 1283, 1290 (Fed. Cir. 2015) ("Samsung's argument on this issue has been sufficiently consistent to negate a finding of waiver."). Indeed, the need for a formal construction of the "angled hole" limitations only became apparent after the Board relied on Arnould alone and adopted the "axis of the third hole" concept, an argument not made by either party below.

b. Unlike the Board's Construction, the Intrinsic Evidence Expressly Distinguishes Between Angled Holes and Angled Tabs

The Challenged Patents clearly and unambiguously describe two separate bone plate embodiments, each having a formation that orients at least one screw at an angle with respect to the bone plate to enhance compression between two bone parts. Appx108(1:35-49). In one embodiment, the formation is "a *tab* that is angled according to an angle between 30° and 60°, and having a hole for engaging the screw." Appx108(1:40-42), Appx108(2:1-7). In the other embodiment, the formation is "a *hole* angled at an angle between 30° and 60° for engaging the screw."

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¹ All citations to the patent specification in Section I are to the '713 patent, which shares the same specification as the '751 patent.

Appx108(1:45-46), Appx108(2:8-10). In both embodiments, "the formation is located on a determined portion of the length of the plate so that the screw ensures the compression of the two bone parts." Appx108(1:47-50), *see also* Appx108(2:4-7). OsteoMed's Response inexplicably dubs the angled tab embodiment "the preferred embodiment," barely acknowledging the existence of the angled hole embodiment. Section I.A.1.b.

By construing [32f] to require only that "the axis of the third hole" is angled relative to the longitudinal axis of the plate, and that the third hole "extend through" a thickness in the plate, the Board effectively rewrote the claim to cover a formation having either an angled tab or an angled hole. Appx18-19, see also Appx76. But Applicant expressly pursued the angled hole embodiment, selecting plain language reciting that the third hole itself is both angled relative to the longitudinal axis of the plate and angled through the thickness of the plate.² Appx110(cl.32), see also Appx117(cls. 1, 17). Claim 32 nowhere discusses the "axis" of the third hole, which cannot and should not be read into the claim. Surgalign Spine Techs., Inc. v. LifeNet Health, No. 2021-1117, 2022 WL 1073606, at *6 (Fed. Cir. Apr. 11, 2022) (reversing the Board's added limitation creating an erroneous "as-applied"

² On the other hand, claims 1 and 16 of the '713 patent are expressly directed to the angled tab embodiment, reciting an "extension...positioned below a bottom surface of the plate" and a "tab angled relative to a longitudinal axis of the plate." Appx108-109(cl. 1, 16).

construction"); *Promos Techs., Inc. v. Samsung Elecs. Co. Ltd.*, 809 F. App'x 825, 833 (Fed. Cir. 2020) (rejecting claim construction that attempted to import the narrower characteristics of an embodiment into an unrelated claim term), *see also* Appx117(cls. 1, 17).

OsteoMed argues that the prosecution history somehow confirms that [32f] broadly encompass both "an angled hole bored into the body of the plate" and what it misleadingly describes to be "an angled hole on a tab." ECF 27, 22. According to OsteoMed, the hole on the angled tab is a *subset* of the angled hole. ECF 27, 23. Contrary to OsteoMed's argument, the specification and prosecution history³ confirm that the angled tab and the angled hole are subsets of the bone plate "formation" that orients the screw at an angle across the fracture or joint. Appx108(1:35-49), Appx4919, Appx4948-Appx4950. The intrinsic evidence specifically avoids describing the hole on the angled tab as "angled," preventing confusion between the embodiments. Even early claims describing the angled tab embodiment in the parent application recited "a central *axis* of the third hole is angled with respect to a longitudinal axis" rather than referring to the third hole as

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³ Contrary to OsteoMed's suggestion (ECF 27, 22-23), a restriction requirement from a parent application does not carry over to a continuation application. *Bristol-Myers Squibb Co. v. Pharmachemie B.V.*, 361 F.3d 1343, 1349–50 (Fed. Cir. 2004).

"angled." Appx4955(cl.26), Appx4957(cl.36), Appx4959(cl. 41), Appx4961(cl. 49), Appx4971.

Importantly, the Challenged Claims are not directed to an angled "formation." With the exception of claim 11 of the '751 patent,⁴ they are directed to a "third hole being angled," *i.e.*, an angled hole. Appx108(1:45-46, 2:8-10), Appx110(cl.32), *see also* Appx117(cls. 1, 17). Applicant was perfectly capable of drafting claims that could reasonably be read to cover both embodiments, but chose not to do so here. Appx4841, *Ventana Med. Sys. v. BioGenex Labs., Inc.*, 473 F.3d 1173, 1181–82 (Fed. Cir. 2006) (recognizing that "each claim does not necessarily cover every feature disclosed in the specification").

c. Stryker's Construction Does Not Violate the Tenet Against Excluding the "Preferred Embodiment"

By failing to acknowledge that the Challenged Patents unambiguously disclose two separate embodiments, OsteoMed complains that Stryker's construction violates the tenet against excluding the preferred embodiment. However, as this Court makes clear, where, as here, "the patent describes multiple embodiments, every claim does not need to cover every embodiment. *This is particularly true when the plain language of a limitation of the claim does not*

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⁴ Claim 11 of the '751 patent expressly recites "said third and fourth hole having an axis that is configured to cross the fracture or joint" and does *not* claim an "angled hole." That language thus potentially encompasses both the angled tab and the angled hole embodiments. Appx117(cl.11).

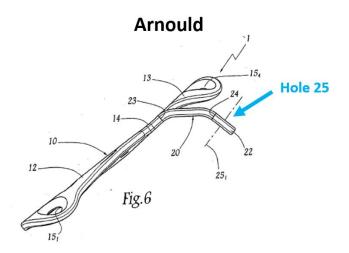
appear to cover that embodiment." Apple Inc. v. Andrea Elecs. Corp., 949 F.3d 697, 708 (Fed. Cir. 2020). Indeed, "disclosed embodiments may be within the scope of other allowed but unasserted claims." *PSN Illinois, LLC v. Ivoclar Vivadent, Inc.*, 525 F.3d 1159, 1166 (Fed. Cir. 2008). Here, the Challenged Claims recite a "third hole being angled," which is clearly directed to the angled hole embodiment, not the angled tab embodiment. Appx110(cl. 32), Appx108(1:45-46, 2:8-10), Appx117(cls. 1, 17), see Barrday, Inc. v. Lincoln Fabrics Inc., No. 2022-1903, 2023 WL 7871688, at *4 (Fed. Cir. Nov. 16, 2023).

This Court should reject OsteoMed's straw man argument that Stryker's construction of the "third hole being angled" somehow excludes "an angled hole on a tab," assumes that an angled tab is not part of the plate, and ignores the "relative to the longitudinal axis of the plate." ECF 27, 20, 22, 24, 26, 27. It does not. Consistent with the plain language of the claims and the intrinsic evidence, which repeatedly differentiate between a "tab" being angled and a "hole" being angled, Stryker asks only that the Court require that the "third hole" itself be angled. Section. I.A.1.a-b.

2. Under a Proper Construction, Arnould Alone Does Not Teach an Angled Hole

The Board's obviousness analysis as to Arnould alone is premised on its erroneous claim construction. Appx19, Appx76. While Stryker does not dispute that Arnould depicts the *axis* of hole 25 to be angled because leg 20 is angled, hole

25 is not itself "bored at an angle" or otherwise described as being angled. Rather, Arnould depicts hole 25 as extending perpendicularly through leg 20, with "the same shape and geometry of holes 15_1 , 15_2 , 15_3 , and 15_4 ." Appx2136-2138(¶¶188-189), Appx4277-4279(¶¶272-273), Appx1161-1162(¶27), Appx1167-1170(Figs. 1-7).



Nor does OsteoMed dispute this. OsteoMed argued below that "the *trajectory* of the third *fixation member*, and therefore the third hole, is angled relative to the longitudinal axis of the plate." Appx203, Appx3196. Stryker's expert explained the error in OsteoMed's logic; namely, that factors such as the size and shape of the screw head may permit the screw trajectory to be angled, *regardless* of whether the hole is angled. Appx2136-2138(¶185-189), Appx4276-4279(¶270-273). Unable or unwilling to respond, OsteoMed relied solely on attorney argument on reply, pivoting to the same comparison it now makes between an inverted drawing of Arnould's hole 25 on leg 20 and hole 1a1 on angled tab 1a of the Challenged Patent. ECF 27, 30, Appx467. But, as this Court has long held, obviousness is not

determined by comparing the prior art (Arnould) to a patent figure. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1053 (Fed. Cir. 1988) (reversing the district court's erroneous comparison of "specification figures with the prior art to determine...patentability"). In any event, Arnould does not disclose the properly construed "angled hole" limitation because hole 25 is not angled, even if leg 20 is. Appx2136-2138(¶185-189), Appx4276-4279(¶270-273).

The Board found that Arnould additionally discloses the "angled hole" limitation because "the inner surface of hole 25 is angled relative to the longitudinal axis of the plate." Appx19, Appx76-77. In an attempt to excuse the Board's unsupported fact finding, OsteoMed now argues that its Petition originally suggested this, even though the Petition acknowledged the concave inner surface of hole 25 only in arguing a *different* claim element: [32e], "a head of the third fixation member is seated in the third hole." ECF 27, 31(citing Appx201).

This Court should reject the Board's improper injection of both the "axis of the hole" and "concave inner surface" theories. Such findings violated the APA, and deprived Stryker of any opportunity to respond. 5 U.S.C. §§ 554(b)(3)-(c); *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016); *Oren Techs.*, *LLC v. Proppant Express Invest., LLC*, No. 2019-1778, 2021 WL 3120819, at *4-5 (Fed. Cir. July 23, 2021).

3. The Board's Obviousness Finding is Improperly Premised on Mr. Sherman's Conclusory Opinion that All Joint Fusion and Fracture Fixation Plates are Interchangeable

Contrary to OsteoMed's arguments, obviousness is not established "merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). Nor is Mr. Sherman's overbroad, conclusory testimony sufficient to demonstrate a motivation to combine with a reasonable expectation of success. *See TQ Delta, LLC v. CISCO Systems, Inc.*, 942 F.3d 1352, 1358-59 (Fed. Cir. 2019).

a. OsteoMed Identifies No Substantial Evidence to Support Obviousness Based on Arnould in view of Zahiri

OsteoMed provides a list of bullet point "highlights" of Mr. Sherman's declaration that purport to bolster the conclusory "interchangeability" testimony that forms the basis of the Board's finding that a POSITA would be motivated to combine Zahiri's angled hole with Arnould. ECF 27, 39-42. But each alleged "highlight" falls woefully short of constituting "substantial evidence."

- ECF 27, 39(citing Appx818, ¶191): The testimony that Arnould and Zahiri disclose plates with diagonal fixation members was offered and relied upon only to support a finding that the references are analogous art, a point that is not on appeal.
- ECF 27, 39-40(citing Appx818, ¶191): The "no practical differences" and "interchangeability" testimony is not *additional* evidence—it is the very testimony that improperly forms the basis for the Board's obviousness finding. ECF 20, 32-34.

• ECF 27, 40(citing Appx821, ¶194): The testimony about plate alignment is relevant only to temporary fixation and has no bearing on the angled hole limitations.

• ECF 27, 40(citing Appx831, ¶216, ¶221): This testimony was specifically called out by the Board in its Institution Decision as "lack[ing] detail." Appx327.

If anything, OsteoMed's paltry citations underscore the conclusory nature of Mr. Sherman's testimony. *See ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1327 (Fed. Cir. 2012) (rejecting expert opinion that failed to explain "how any specific combination would operate or read on the asserted claims").

Similarly, OsteoMed's attempt to distinguish *TQ Delta*, 942 F.3d 1352, falls flat. ECF 27, 42-43. For example, the opinion that Zahiri "allows a sufficient amount of force to be applied between bone parts while dissipating the force so that it does not damage the bone parts" is merely a recitation of what is taught in Zahiri and is nonresponsive as to why a POSITA would be motivated to combine Zahiri and Arnould. Appx820(¶193), Appx3715(¶133), Appx3755-3756(¶249). Indeed, the Board expressly relies on Mr. Sherman's "interchangeability" testimony as the sole motivation to combine Arnould and Zahiri, which "fails to explain why a [POSITA] would have combined elements from specific references *in the way the claimed invention does*." Appx22, Appx26, Appx80-81, Appx85-86, *TQ Delta*, 942 F.3d at 1362 (original emphasis). Such conclusory testimony is insufficient to support an obviousness determination. *Id.* at 1362.

b. Without Explanation, the Board Improperly Ignored Dr. Holmes' Rebuttal Testimony Regarding Alleged "Interchangeability"

Stryker's expert, Dr. Holmes, explained why Arnould and Zahiri are *not* interchangeable. Appx2186-2187(¶¶54-56), Appx4331-4332(¶¶54-56). OsteoMed contends that the Board "repeatedly refer[red] to the testimony of Appellant's experts," "weigh[ed] that testimony against Appellee's expert," and concluded that Mr. Sherman was more credible. ECF 27, 43-44. But none of OsteoMed's cites to the Board's FWD relate to Dr. Holmes' testimony on interchangeability.⁵

As in *Google*, the Board failed to "acknowledge any of [Stryker's] evidence, let alone explain why it considered such evidence unconvincing." *Google Inc. v. Intell. Ventures II LLC*, 701 F. App'x 946, 954 (Fed. Cir. 2017). Where, as here, there is a "close factual dispute⁶ where reasonable minds may differ in their findings based on opposing evidence, the Board must provide [a] rationale for its findings to facilitate our review." *Id.* at 955. The Court should, at a minimum, vacate and

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⁵ Appx10, Appx20, Appx23, Appx24, Appx33, Appx60, Appx63-64, Appx77, Appx82, Appx98 relate solely to Mr. Leinsing. Appx41, Appx39, and Appx92 reference both Mr. Leinsing and Dr. Holmes, but only address temporary fixation.

⁶ As in *Google*, there is a "close factual dispute" because in the companion cases, OsteoMed took the opposite position as Mr. Sherman; namely, that a bone plate for use with fraction fixation is not interchangeable for use with joint fusion. Appx4371-4380, Appx2425, Appx2427-2428, Appx5173-5175.

remand to the Board to address Dr. Holmes' testimony, taking into consideration Mr. Sherman's failure to rebut such testimony.

c. OsteoMed Does Not Reconcile the Inconsistencies with Companion Cases

OsteoMed has not and cannot reconcile Mr. Sherman's "no practical differences" and "interchangeability" opinions with the positions it took in the companion cases relating to the Falkner prior art. ECF 27, 44-45. That Falkner is an anticipatory reference does not explain away OsteoMed's disparate positions. Mr. Sherman's opinions were not tethered to Arnould or Zahiri, so there is no reason why his opinions would not also apply to Falkner. In the companion cases, the Board granted (over OsteoMed's objection) Stryker's motion to submit the Sherman Declarations as supplemental information because the testimony provided "background knowledge and perspective" regarding the alleged lack of differences between fixing fractures and fusing bones across a joint. Appx2424-2428.

The Board in the companion cases nevertheless declined to find Falkner anticipatory, failing to acknowledge Mr. Sherman's "no practical differences" and "interchangeability" testimony or Falkner's express statement that the same bone plate, without modification, could be used for fracture fixation and joint fusion of the ankle. In contrast, in the present IPRs, the Board relied on Mr. Sherman's "no practical differences" and "interchangeability" testimony as the centerpiece of its motivation to combine Arnould's plate for a toe joint with Zahiri's disparate guide

plate for a shoulder fracture. Appx22, Appx26, Appx80-81, Appx85-86. Such findings are contradictory and cannot be reconciled.

Further, OsteoMed takes the absurd position on appeal that it would be a "trivial task" to incorporate the fixed angle bore of Zahiri's shoulder fracture guide plate into a flexible leg appended to Arnould's toe joint plate. ECF 27, 48. Ignoring that this was nowhere argued below,⁷ this position cannot be reconciled with OsteoMed's winning position in the companion cases that the Falkner plate cannot be repositioned across the ankle joint without "extensive modifications" to the bone plate itself, notwithstanding Falkner's express disclosure that the same plate can be used across both an ankle fracture and an ankle joint. OsteoMed cannot have it both ways.

d. The Board Improperly Excused OsteoMed from its Burden of Demonstrating a Reasonable Expectation of Success

This Court recognizes that "it [is], at all times, [Petitioner's] burden to show that the claims would have been obvious, including that a skilled artisan would have had a reasonable expectation of success in achieving the claimed invention." *Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 8 F.4th 1331, 1348 (Fed. Cir. 2021). OsteoMed rallies behind the Board's own unsupported finding that modifying

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⁷ OsteoMed cites to ¶193 ('713 patent) and ¶¶248-249 ('751 patent) but those excerpts simply recite Mr. Sherman's familiar "no practical differences" and "interchangeability" testimony.

Arnould's hole to incorporate Zahiri's angled hole configuration would be a "relatively minor change" and that "[t]here is no indication this configuration would **not** work if adapted to and sized for the dimensions of Arnould's plate and the anatomy of the metatarsal-phalangeal joint." Appx26, Appx85-86. The Board relies solely on Mr. Sherman's familiar "no practical differences" and "interchangeability" testimony without specifically addressing a reasonable expectation of success. ECF 27, 48-49, Appx22, Appx85-86.

In contrast, Stryker provided evidence from two experts describing why Zahiri's angled hole configuration would not work with Arnould's plate—testimony that fell on deaf ears. Appx2125-2136(¶167-184), Appx2185-2190(¶51, 54-56, 63-66), Appx4259-4273(¶239-264), Appx4330-4335(¶51, 54-56, 63-66). By its own words, the Board turned the burden of proof on its head, excusing OsteoMed from demonstrating that the proposed Arnould-Zahiri combination *would* (or even could) work while at the same time, rejecting without explanation Stryker's evidence proving that the combination would not work. *Magnum*, 829 F.3d at 1376 ("[I]t is inappropriate to shift the burden to the patentee after institution to prove that the patent is patentable.").

Reversal is required as no substantial evidence supports the Board's finding for the combination of Arnould and Zahiri.

B. The Board's Analysis of the Temporary Fixation Step of Dependent Claim 38 was Unsupported by Substantial Evidence

The Board's obviousness findings as to dependent claim 38 are unsupported by substantial evidence.

As Petitioner, OsteoMed had the burden of identifying "in writing and with particularity . . . the grounds on which the challenge to each claim is based." 35 U.S.C. § 312(a)(3). OsteoMed's Petition challenged claims of the '713 patent based on the combination of Arnould and Zahiri (Ground 4), not Arnould alone. When asked at oral argument to clarify its Ground 4 position, OsteoMed's counsel stated "I believe that Claim 38 of the 487 proceeding – the '713 patent – relates to the guide pin holes and we've said that Arnould discloses those holes with the knowledge of a POSITA, but I do think that we rely more on Zahiri for that claim." Appx633(21:2-14). Even though OsteoMed literally told the Board that it was "rely[ing] more on Zahiri" for claim 38, the Board still found obviousness based on Arnould alone.

The Board erred by relying solely on Mr. Sherman's speculative and unsupported testimony pronouncing that two circles appearing without explanation in an Arnould figure are "pin holes intended to be used to temporarily secure the plate with k-wires during the implantation process." Appx36-39, Appx820-Appx821(¶194). There is no dispute that Arnould nowhere identifies or discusses the circles. Nor does Arnould describe or mention the use of temporary fixation

pins, let alone a method of inserting a temporary fixation pin as set forth in claim 38.

Instead, Arnould describes in detail a *different* method of plate alignment using a partially-inserted screw in an oblong hole to partially immobilize the plate. As discussed *infra* at Section II.C.2, it is undisputed that there is simply *no* evidence, let alone substantial evidence, to support the Board's finding that Arnould's partial immobilization method "does not obviate the motivation to use k-wires or incorporate Zahiri's temporary fixation pins to further immobilize the plate, either before or after the insertion of screw 2, to ensure correct alignment." Appx41. Reversal and remand is appropriate.

II. THE COURT SHOULD REVERSE OR VACATE THE BOARD'S FINDING FOR THE '751 PATENT (GROUNDS 4 AND 5)

THEREFORE

In IPR2022-00488, like IPR2022-00487, OsteoMed alleged five separate grounds of alleged obviousness:

STATEMENT OF PRECISE RELIEF REQUEST AND REASONS

Ground	Basis	Relied-On References	Claim(s)
1	§103	WIPO Pat. Pub. No. WO 2007/131287A1 to Slater ("Slater") (Ex. 1004)	1, 2, 7, 8
2	§103	Slater and U.S. Pat. No. 8,187,276 to Zahiri et al. ("Zahiri") (Ex. 1007)	1-2, 7-18
3	§103	Slater, Zahiri, and U.S. Pat. Pub. No. 2006/0241592 to Myerson ("Myerson") (Ex. 1010)	6
4	§103	E.P. Patent No. 1,897,509 to Arnould ("Arnould") (Ex. 1005-1006) and Zahiri	1-3, 7-18
5	§103	Arnould, Zahiri, and Myerson	6

Appx3131, Appx53-54, Appx100. Again, none of the grounds included Arnould alone.

The Board's obviousness finding for *each and every* Challenged Claim of the '751 patent must be vacated and remanded if Stryker demonstrates either that (1) OsteoMed simply did not address the "third hole located between said first hole and said second hole" claim element; or (2) the Board improperly construed the word "between."

The Board's obviousness finding for claims 1-3, 6-10, and 17-18 must be reversed and remanded if this Court finds that the Board legally erred in changing the meaning of the "angle hole" limitations [1d] and [17d] by requiring only that the *axis* of the third hole is angled.

The Board's obviousness finding for claims 11-18 must be reversed and remanded if Stryker demonstrates that there is no substantial evidence to support the Board's finding that Arnould alone (not argued in the Petition) or Arnould in view of Zahiri render obvious the "temporary fixation" limitations ([11e], [11i], and [17e]).

Independent claim 17 suffers from the additional problem that OsteoMed's Petition fails to specify its Ground 4 arguments with reasonable particularity such that no reasonable fact finder could find the Board's obviousness finding to be supported by substantial evidence. Similarly, the Board's obviousness finding

relating to dependent claim 6 cannot stand because it is based on the Board's mistaken reliance on the wrong Myerson prior art reference.

- A. The Board's Analysis of the "Between" Limitation ([1d], [11d], [17d])⁸ was Both Legally Erroneous and Unsupported by Substantial Evidence
 - 1. The Board's Implicit Construction of "Between" was Legally Erroneous

Without actually articulating the Board's construction, OsteoMed repeatedly argues that the Board "properly construed" the term "between." ECF 27, 50-55. But the Board did not explicitly define "between"—it simply rejected Stryker's ordinary meaning construction and found that Arnould alone discloses it. This is particularly egregious because OsteoMed's Petition nowhere argues that Arnould alone discloses a third hole located "between" a first hole and second hole: OsteoMed argued only that Zahiri disclosed this element. Appx3195-3198, *see infra* at Section II.A.2.

OsteoMed argues that, other than being "between" the first hole and second hole, the claims recite "no additional limitation as to location." ECF 27, 51. This ignores that claim 1 recites that the claimed bone plate has "a length defining a longitudinal axis," and "a first end and a second end *along said length*," with the bone plate "defining" "a first hole at or adjacent the first end," "a second hole at or adjacent the second end," and "a third hole located between said first hole and said

⁸ The Board did not differentiate between claims 1, 11, and 17 for the "between" limitation. Appx87, Appx95.

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second hole." Such claim language confirms that the third hole, like the first and second holes, must also be along said "length defining a longitudinal axis" and cannot be "offset" from such "length" as OsteoMed and the Board suggest. Appx117(cl.1), ECF 20, 51-53, Appx64. Indeed, the specification explains that the "formation is located *on* a determined portion of *the length of the plate* so that the screw ensures compression of the two bone parts," and that the plate "*has a hole* for engaging a screw and *is located in the central part of the width, over a determined part of the length of the plate.*" Appx116(1:56-59), Appx111(Abstract).

As it did below, OsteoMed relies on the angled tab embodiment, ¹⁰ characterizing the tab as being "in a different plane than the main body" and "offset." ECF 27, 52, Appx64. This argument, later accompanied by an improper comparison of Figure 2 of the '751 patent with an inverted version of Figure 5 of the Arnould patent, was intended to leave the misimpression that Arnould's leg is offset in the same manner as the angled tab. Appx3503, ECF 27, 59. But rather than being "offset," the '751 patent describes the angled tab as being "positioned *along the length of the plate*." Appx116(2:15-16). In contrast, Arnould's leg projects off to

⁹ Claims 11 and 17 similarly claim "a bone plate having a *length* sufficient to span a fracture or joint." Appx117(cls. 11, 17).

¹⁰ As discussed *supra* in Sections I.A.1-2, OsteoMed's argument also wrongly assumes that the Challenged Claims must cover the angled tab embodiment.

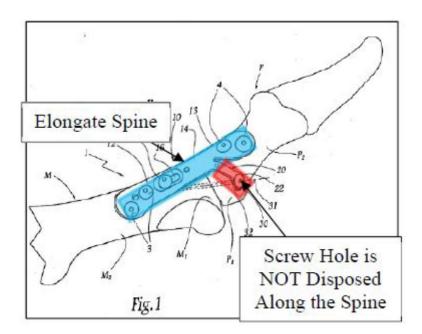
the side of the main Arnould plate body. Appx1379(151:14-20), Appx4274-4276($\P 268$).

Finally, OsteoMed's waiver argument with respect to the proposed construction of "between" (ECF 27, 55) is contrary to this Court's precedent. This Court recognizes that "[t]he doctrine of waiver does not preclude a party from supporting its original claim construction with new citations to intrinsic evidence of record." *Seabed Geosolutions (US) Inc. v. Magseis FF LLC*, 8 F.4th 1285, 1289 (Fed. Cir. 2021); *see also Interactive Gift Exp., Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1346 (Fed. Cir. 2001) (same).

2. No Substantial Evidence Supports the Board's Finding that Arnould Alone Discloses the "Between" Limitation

OsteoMed's Petition nowhere argued that Arnould alone discloses the "between" limitation. Appx3195-3198, Appx3204, Appx3209. Attempting to demonstrate otherwise on appeal, OsteoMed cobbles together annotated figures from different claim elements [1b] (Appx3194), [1c] (Appx3195), and [17g] (Appx3210), arguing that the images somehow address the "between" limitation. ECF 27, 56-57. This is not substantial evidence. Nor can OsteoMed properly rely on its Reply to backfill arguments improperly ignored in the Petition. Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc., 853 F.3d 1272, 1286 (Fed. Cir. 2017) ("Continental did not make out its obviousness case in its petition").

OsteoMed does not deny that it made a strategic decision to not provide any "between" arguments in its Petition to avoid the appearance of inconsistency in the companion cases on appeal. However, *after* oral argument in the companion cases, OsteoMed conceded below that if Arnould's hole is "indeed disposed along the spine of the plate, then the third hole is also between the first and second holes." Appx3503-3504. But the Board in the companion cases, prompted by OsteoMed, found that Arnould's hole 25 "is not disposed on the spine, but part of a separate leg piece that extends off the spine." Appx4385-4386.

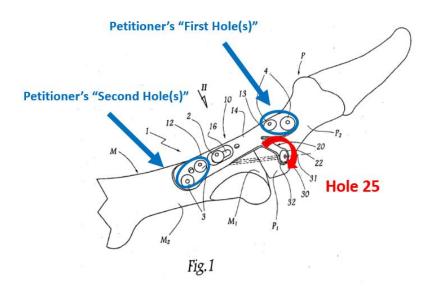


Appx4386. For the same reason, hole 25 cannot be between a first hole and second hole along the length of the bone plate.

Finally, OsteoMed argues that "even under Appellant's construction," Arnould's hole falls within the scope of "between," once again comparing a doctored

Figure 5 of Arnould to Figure 2 of the '751 patent. ECF 22, 59, Appx74-75. As discussed above, it is wholly improper to compare "specification figures with the prior art to determine the patentability of the invention." *Uniroyal*, 837 F.2d at 1053. As more easily shown in Figure 1, Arnould's hole 25 falls outside the scope of "between" because it is positioned at the distal end of leg 20, which is itself "offset" from the length of the bone plate. Appx1160-1161(¶¶23, 26), Appx4273-4276(¶¶266-269), Section II.A.1.

Arnould



3. OsteoMed Failed to Address Any Motivation to Combine Arnould with Disparate Zahiri Embodiments

OsteoMed improperly cobbled together disparate embodiments of Zahiri for the "between" limitations and the "angled hole" limitations. As discussed below in Section II.B., OsteoMed failed to provide any motivation to combine such embodiments.

B. The Board's Analysis of the "Third Hole Being Angled" Limitations ([1d], [17d]) was Legally Erroneous and Unsupported by Substantial Evidence

Like claim 32 of the '713 patent, claim 1 recites "said third hole is angled relative to the longitudinal axis of said bone plate, but it does not include the claim language "through the thickness of the plate." ECF 27, 24. For the reasons discussed above in Section I.A.1-2, in light of the intrinsic evidence, simply claiming the "hole being angled," is all that is necessary to clarify that the claim is directed to a hole that is angled, not a tab that is angled. *Apple*, 949 F.3d at 708. Under a correct claim construction, there is no substantial evidence to support the Board's obviousness findings. Section I.A.1-3.

Additionally, Stryker notes that OsteoMed does not dispute that it failed to provide evidence of a motivation to combine different Zahiri embodiments in its obviousness analysis. ECF 22, 60-63, *see In re Stepan Co.*, 868 F.3d 1342, 1345-46 n.1 (Fed. Cir. 2017). In the absence of any evidence, the Board's argument that the "principles" in Zahiri's figures "can be applied in many possible embodiments" is of its own making, neither supported by substantial evidence nor demonstrative of a motivation to combine. Appx85(n.10), *Alacritech, Inc. v. Intel Corp.*, 966 F.3d

¹¹ For claim 17, the Board relied on its discussion of claim 1 regarding the "angled hole" limitation. Appx94-95.

1367, 1372 (Fed. Cir. 2020) ("[T]he Board's reasoning appears to be untethered to either party's position.").

Finally, for the same reasons described in Section I.A.2-3, the Board's factual finding is unsupported by substantial evidence and must be reversed or vacated and remanded.

C. The Board's Analysis of the Temporary Fixation Limitations ([11e], [11i], [17e])¹² was Unsupported by Substantial Evidence

The Board's obviousness finding should be reversed and remanded because no substantial evidence supports a finding that Arnould discloses temporary fixation members and/or that a POSITA would have been motivated to combine Zahiri's temporary fixation pins for use with Arnould's plate.

1. OsteoMed Relied on Zahiri, Not Arnould, for the Temporary Fixation Limitations of the '751 Patent

OsteoMed's Response once again attempts to shift focus from its Ground 4 Arnould and Zahiri combination, disingenuously arguing that it put forth "undisputed evidence that Arnould alone disclosed the Temporary Fixation Limitations." ECF 27, 33-34.

But OsteoMed's Petition addressing the '751 patent *nowhere* argued that Arnould alone discloses the Temporary Fixation Limitations. Appx3204-3205,

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¹² As OsteoMed concedes, dependent claims 9 and 10 of the '751 patent raise the same concepts as claims 11 and 15-18. ECF 27, 33, n.6.

Appx3207-3208, Appx3211-3212, Appx3214, Appx3190-3191. Both OsteoMed and its expert Mr. Sherman candidly admitted that "Arnould lacks sufficient disclosure regarding temporary fixation members in the guide holes" and suggested that "a POSITA would look to prior art in the relevant field, like Zahiri, for this disclosure." Appx3191, Appx3207-3208, Appx3211-3212, Appx3214, Appx3756-3757(¶¶251-252). OsteoMed's 3-page Reply addressing Ground 4 of the '751 patent glossed over the "temporary fixation member" recited in [11i], stating only that "Arnould itself discloses pin holes." Appx3505-3506. This is hardly "undisputed evidence that Arnould alone discloses the Temporary Fixation Limitations." Indeed, OsteoMed told the Board that "we've said that Arnould discloses those holes with the knowledge of a POSITA, but I do think that we rely more on Zahiri for that claim; and the same would be true then of the '751 patent with respect to the guide pin holes, we rely on Zahiri..." Appx633(21:2-14).

In view of its representations to Stryker and the Board, OsteoMed should not be permitted to proceed on an "Arnould-only obviousness" ground brought out belatedly on reply, or worse, on appeal. *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1330-31 (Fed. Cir. 2019) ("[A]n IPR petitioner may not raise in reply 'an entirely new rationale' for why a claim would have been obvious.").

2. No Substantial Evidence Supports the Board's Finding that Arnould Alone or in Combination with Zahiri Render Obvious the Temporary Fixation Limitations

OsteoMed concedes that Arnould does not disclose temporary fixation members ([11i] and cl. 18 of '751 patent and cl. 38 of '713 patent). Appx3204-3205, Appx3207-3208, Appx216-217. OsteoMed further concedes that Arnould nowhere describes pin holes used for temporary fixation ([11e], [17e]). ECF 27, 9. Yet the Board's obviousness finding is wholly based on crediting Mr. Sherman's speculative, unsupported opinion that two unidentified, unreferenced circles shown in Arnould Figure 2 depict "temporary guide holes that may be used to temporarily secure the plate." Appx90-91, Appx39-41.

The Board was so enamored with Mr. Sherman's bare statement dubbing the unreferenced circles as pin holes that it refused to give credence to Arnould's express disclosure. In particular, Arnould expressly describes its preferred surgical technique of partially immobilizing the plate on the metatarsal in a manner that allows for relative freedom of movement along the longitudinal direction of the plate body prior to inserting the long screw through the leg of the plate. Appx1156-1157(¶8), Appx1162(¶31). Stryker's experts provided *unrebutted* testimony that the size and shape of Arnould's bone plate, together with Arnould's procedure for partially immobilizing its plate in a manner allowing for guided movement, *negates* any need for temporary fixation pins in specially designed pin holes. Appx2133-

Appx2143-2144(\P 202-205), $2135(\P 181-182),$ Appx2180-2182(\P 43-45), Appx2189-2190(\P 63-66), Appx4267-Appx4269(¶¶251-255), Appx4284-Appx4286-Appx4296 Appx4285(¶285), $(\P 291-293,$ 301-312, 319-322), Appx4325-Appx4327(¶¶43-45), Appx4334-Appx4335(¶¶63-66). Mr. Sherman failed to respond to Stryker's experts, declining to address Arnould's express disclosure of a *different* procedure for plate alignment using partial immobilization, or to explain why a POSITA would be motivated to use Zahiri's temporary locking pins in the Arnould plate, which would restrict the guided movement that Arnould deems important.

The Board nevertheless found that Arnould's partial immobilization "does not obviate the motivation to incorporate Zahiri's temporary fixation pins to further immobilize the plate, either before or after the insertion of screw 2, to ensure correct alignment." Appx92, Appx41. But as discussed above, OsteoMed offered no evidence to rebut Stryker's evidence that Arnould's partial immobilization does obviate the need for temporary fixation pins. The Board cannot simply make its own unsupported fact-findings, especially in view of unrebutted evidence to the contrary. In re Zurko, 258 F.3d 1379, 1386 (Fed. Cir. 2001) ("[T]he Board cannot simply reach conclusions based on . . . its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings."); K/S Himpp v. Hear-Wear Techs., LLC, 751 F.3d

1362, 1365-66 (Fed. Cir. 2014) (missing limitations cannot be established with "conclusory assertion[s]...about general knowledge in the art without evidence on the record").

Instead of criticizing Mr. Sherman for failing to address Arnould's express disclosure of a different procedure for temporary fixation, the Board improperly shifted the burden to Stryker to disprove that the unreferenced and unexplained circles in the Arnould figures were pin holes. Appx91, Appx40, Magnum, 829 F.3d at 1378 ("The Board improperly shifted the burden to Magnum to disprove obviousness"). But there was simply no basis for Stryker's experts to speculate as to the myriad of possible reasons for their inclusion in the Arnould figure (i.e., storage, sterilization, draftsman's error, etc.). Moreover, since Arnould is silent as to the unreferenced circles and there is no evidence that Arnould was ever commercially available, Mr. Sherman's self-serving identification of such circles, without more, was pure speculation. The Board erred by relying on Mr. Sherman's unsupported testimony and OsteoMed's attorney-annotations as conclusive proof that Arnould discloses pin holes intended for use with temporary fixation members, when Arnould's express disclosure and Stryker's well-reasoned expert opinions demonstrated otherwise. In re Warsaw Orthopedic, Inc., 832 F.3d 1327, 1335 (Fed. Cir. 2016) ("The PTAB's conclusory assertion that Figure 5 of Jacobson 'appears

to' support its finding does not equate to the reasoned explanation needed to support its conclusion.").

D. OsteoMed's Analysis of Claim 17 Violated 35 U.S.C. § 312(a)(3)

OsteoMed's Ground 4 argument for claim 17 of the 751 patent was incomprehensible. *See* ECF 20, 68-70. OsteoMed contends that, by relying on 35 U.S.C. § 312(a)(3), Stryker "challenges the Board's decision to institute" which is "not appealable." ECF 27, 65. Stryker makes no such challenge. Rather, this Court "review[s] the Board's judgements concerning what arguments have been adequately presented in a petition and other pleadings for abuse of discretion." *Microsoft Corp. v. IPA Techs. Inc.*, No. 2021-1412, 2022 WL 989403, at *2 (Fed. Cir. Apr. 1, 2022).

While OsteoMed attempts to excuse its cryptic claim 17 analysis as involving a mere "mismatch" between the section headings and the claim appendix attached to the Petition, the incomprehensible nature of the Petition extends well beyond that. Contrary to OsteoMed's contentions, none of the headings for Ground 4 state "the first few words" of any limitation for claim 17. ECF 27, 66 (citing table of contents).

c.	Inde	ependent Claim 17		
	i.	[17Pre]82		
	ii.	[17a]82		
	iii.	[17b]83		
	iv.	[17c]83		
	V.	[17d]83		
	vi.	[17e]83		
	vii.	[17f]83		
	viii.	[17g]84		
	ix.	[17h]85		
	X.	[17i]85		
	xi.	[17j]86		

Appx3120-3122. Nor do the section headings in the body of the Petition contain "the first few words" of the limitations, as OsteoMed argues:

iii. [17b]

For at least the reasons in Section VII.F.2.a.ii, Arnould discloses this element.

(Ex. 1006, ¶14; Ex. 1002, ¶308).

iv. [17c]

For at least the reasons in Section VII.F.2.a.iii, Arnould discloses this element.

(Ex. 1006, FIG. 1, ¶21, 34; Ex. 1002, ¶309).

v. [17d]

For at least the reasons in Section VII.F.2.a.iv, Arnould discloses this element.

(Ex. 1006, FIG. 1, ¶21, 33; Ex. 1002, ¶310).

vi. [17e]

For at least the reasons in Section VII.F.2.a.v, Arnould discloses this element.

(Ex. 1006, FIG. 2, ¶32; Ex. 1002, ¶311).

vii. [17f]

Arnould is silent regarding the dimensions of hole 25. A POSITA would look to prior art like Zahiri for disclosure of the known dimensions of such openings. (Ex. 1002, ¶312).

As discussed in Section VII.D.2.c.vii, a POSITA would find that Zahiri discloses this element. (Ex. 1007, 7:35-41; Ex. 1002, ¶313). A POSITA would be motivated to combine the teachings of Arnould and Zahiri to further improve the integrity of the angled fixation screw of Arnould's plate using Zahiri's lag screw. (Ex. 1002, ¶313).

A POSITA would find this element obvious in view of Arnould and Zahiri.

(Ex. 1002, ¶314).

Appx3208-3212.

As discussed in Stryker's Opening Brief and below, the Board's cursory analysis of claim 17 in the Petition and conclusory adoption of OsteoMed's arguments "with reference to claims 1 and 11" was an abuse of discretion, or at a minimum, unsupported by substantial evidence. Appx94-95, *Microsoft*, 2022 WL 989403 at *6; *see also Nichia Corp. v. Document Sec. Sys., Inc.*, No. 2020-2261, 2022 WL 1218036, at *4 (Fed. Cir. Apr. 26, 2022) ("[t]he patent challenger must provide an understandable explanation of the element-by-element specifics of its unpatentability contentions").

E. The Board's Motivation to Combine Arnould, Zahiri, and Myerson '592 is not Supported by Substantial Evidence for Claim 6 of the '751 Patent

OsteoMed does not dispute that the Board blindly relied on the wrong Myerson reference and the error-laden opinions of Mr. Sherman in addressing Ground 5. In dismissing the Board's error as "harmless" (ECF 27, 62), OsteoMed ignores that the Board's motivation to combine was based on its erroneous belief that "Myerson teaches that similar bone plates can be used for both the MTP joint and tarsometatarsal [(TMT)] joint, which supports Mr. Sherman's testimony that a POSITA could easily configure Arnould's bone pla[te] [sic] for the tarsometatarsal joint (Ex. 1002 ¶ 345) and evidences a motivation for doing so." Appx97. But neither Myerson '608 nor Myerson '592 teaches that similar bone plates can be used for both the MTP and TMT joints, nor did Mr. Sherman so opine. Appx1187,

Appx4017, Appx850-853, Appx3789-3791. "If the Board based its decision on a misunderstanding of [Myerson], its conclusions regarding obviousness are called into question." *In re Chapman*, 595 F.3d 1330, 1339-40 (Fed. Cir. 2010).

The Court should reverse because the Board's finding for claim 6 is not supported by substantial evidence.

CONCLUSION

For the above reasons, the Court should reverse or vacate the Board's obviousness findings.

Dated: May 24, 2024

Respectfully submitted,

/s/ Sharon A. Hwang

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Counsel for Appellant

FORM 19. Certificate of Compliance with Type-Volume Limitations

Form 19 July 202

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Cas	se Number:	23-2397, 23-	2398		
Short Case Caption:		Stryker European Operations Holdings LLC v. Osteomed, LLC			
items listed	l as exempte		R. App. P. 5(c	age count, you may exclude any e), Fed. R. App. P. 21(d), Fed. R. R. 32(b)(2).	
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Date: <u>05/2</u>	4/2024	_	Sig ature:	/s/ Sharon A. Hwang	
			Name:	Sharon A. Hwang	